K051337 1/3

510 (k) Summary
Eagle Eye™ Gold IVUS Catheter/Volcano VH IVUS System

Date Prepared: May 20, 2005

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

AUG 1 8 2005

Contact person: Lorry W. Huffman
Director, Regulatory Affairs

Phone number: (916) 638-9404
Facsimile number: (916) 638-8112

Device Name: Eagle Eye™ Gold IVUS Catheter/Volcano VH IVUS System

Classification name:	**Class**
• 870.1200 Diagnostic Intravascular catheter	II
• 892.1560 Ultrasonic pulsed echo imaging system	II
• 892.1570 Diagnostic ultrasonic transducer	II

Predicate Device:
The Eagle Eye™ Gold IVUS Imaging Catheter is substantially equivalent to: Eagle Eye™ IVUS Imaging Catheter (Intravascular Ultrasound Imaging Catheter) cleared under K031346 on June 23, 2003.

The Volcano VH IVUS System is substantially equivalent to: Volcano IVUS System cleared under K042188 on November 10, 2004.

Device Description:
The Eagle Eye catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The Eagle Eye™ Gold catheter utilizes an internal lumen that allows the catheter to track over the 0.014" (0.36mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The Eagle Eye Gold catheter is introduced percutaneously or via surgical cut down into the vascular system.

The Eagle Eye Gold catheters may only be used with the In-Vision™ Imaging System using v4.2 software or higher or v4.2 VH software or higher and can also

used with Volcano VH IVUS System software v1.2 or higher. This catheter will not operate if connected to any other imaging system.

The Volcano VH IVUS (VI) System is a combination of proprietary hardware and software. The system is an accessory device to In Vision Gold, a conventional IVUS device to provide another visualization of the peripheral and coronary vasculature.

The hardware portion consists of a high-speed computer placed on-board the In Vision Gold console, specifically built for use in medical institutions; high-speed analog-to-digital conversion circuitry and proprietary gating circuitry. The system is connected to the conventional IVUS system and the ECG system using typical cabling. The IVUS radiofrequency output is used directly by the Volcano IVUS System and the ECG output is used to gate or time the collection / recording of the IVUS signal.

The software that provides the user interface is Windows 2000 Professional. The Volcano IVUS System comprises a data acquisition module and a data analysis module. The data acquisition module communicates with the analog-to-digital conversion circuitry and manages the joining of the data from individual scans that constitute a "slice". The data analysis module analyzes each of the slices. These images are visually reviewed, a segment for analysis is selected, and vessel inner and outer borders are identified. The black and white IVUS files are processed to produce the five color bit-mapped Volcano IVUS image files.

Intended Use:

The Eagle Eye Gold catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Eagle Eye Gold ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Volcano VH IVUS System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular featues that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

Device Technological Characteristics and Comparison to Predicate Device:
The Eagle Eye™ Gold IVUS Imaging Catheter is substantially equivalent to: Eagle Eye™ IVUS Imaging Catheter (Intravascular Ultrasound Imaging Catheter) cleared under K031346 on June 23, 2003. The Volcano VH IVUS System is substantially equivalent to: Volcano IVUS System cleared under K042188 on

November 10, 2004. Labeling has been revised in order to provide clarifications for the user.

The fundamental scientific technology remains the same.

The Eagle Eye™ Gold IVUS Catheter and Volcano VH IVUS System use the same fundamental scientific technologies and have the same *intended use as that of the predicate devices, Eagle Eye (K031346) and Volcano IVUS (K042188).*

Performance Data:
Applicable testing was performed in accordance with Design Controls including a risk analysis addressing the impact of modifications to the device and components. Results met the predetermined acceptance criteria.

Conclusion:
Eagle Eye™ Gold IVUS Catheter and Volcano VH™ IVUS System have the same *Intended Use* and utilize the same *fundamental scientific technology* as that of the predicate devices, *Eagle Eye (K031346) and Volcano IVUS (K042188).* Modifications to the devices do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the modified device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2007

Volcano Corp.
c/o Ms. Lorry Huffman
Director, Regulatory Affairs
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K051337
Trade/Device Name: Eagle Eye Gold IVUS Imaging Catheter, Model 85900 and Volcano VH IVUS System
Regulation Number: 21 CFR 870.1560 and 870.1200
Regulation Name: System, Imaging, Pulsed Echo, Ultrasonic and Diagnostic, Intravascular, Catheter
Regulatory Class: II
Product Code: IYO and OBJ
Dated: July 11, 2005
Received: July 18, 2005

Dear Ms. Huffman:

This letter corrects our substantially equivalent letter of August 18, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

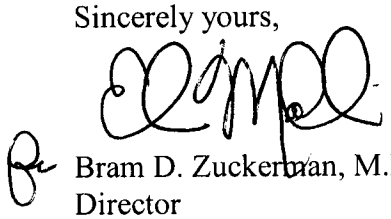
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-4008. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051337

Device Name: Eagle Eye™ Gold IVUS Imaging Catheter and Volcano VH IVUS System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051337